

**Notice of Allowability**

Application No.

09/599,002

Applicant(s)

NYLAND ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Interview concluding 23 September 2004.
2. ☒ The allowed claim(s) is/are 37-74.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date part of 0904.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### SUPPLEMENTAL EXAMINER'S AMENDMENT

1. The instant amendment is supplemental to the Examiner's amendment of 24 March 2004. For the sake of clarity, the amendments set forth below include both the original amendments authorized in a telephone interview with Gordon Kit on 22 March 2004 (and included in the Examiner's amendment of 24 March 2004), and the additional amendments authorized by Drew Hissong in a telephone interview on 23 September 2004, which additional amendments appear in **bold text**.

2. Claims 37-74 are allowed, subject to the Examiner's amendment set forth below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Gordon Kit on 22 March 2004 and with Drew Hissong on 23 September 2004.

4. In accordance with 37 C.F.R. 1.126, allowed claims 37-74 will be renumbered as claims 1-38, respectively (see MPEP 608.01(j)). It is noted that original claim numbers are employed in the below examiner's amendment.

**5. The application has been amended as follows:**

**a) Amend the claims as follows:**

In claim 37, line 5, delete “determined genotype” and insert therefore—genotype determined in step (a)--.

In claim 38, line 3, after “test human subject,” insert—and--.

In claim 38, line 4, delete “(b)” and insert therefore—(b1)--.

In claim 38, line 5, delete “determined genotype” and insert therefore—genotype determined in step (a)--.

In claim 38, line 5, after “NA1/NA1,” delete “and” and insert therefore—or--.

In claim 38, line 6, delete “(c)” and insert therefore—(b2)--.

In claim 38, line 7, delete “determined genotype” and insert therefore—genotype determined in step (a)--.

In claim 39, line 5, delete “determined genotype” and insert therefore—genotype determined in step (a)--.

In claim 40, lines 4-5, delete “cardiovascular disease, atherosclerosis or non-immune related cerebrovascular disease” and insert therefore—a non-immune-related disease wherein the non-immune-related disease is cardiovascular disease, atherosclerosis or cerebrovascular disease”

In claim 40, at lines 5-6, delete “determined genotype” and insert therefore—genotype determined in step (a)--.

In claim 41, line 5, delete “determined genotype” and insert therefore—genotype determined in step (a)--.

**In claim 46, at lines 2-3, delete “prophylactically or”.**

**In claim 46, at line 3, delete “prophylactic or”.**

In claim 47, lines 1-2, delete “the presence of said genetic marker for susceptibility to myasthenia gravis is found” and insert therefore—said genetic marker for susceptibility to myasthenia gravis is present”.

**In claim 47, at line 4, delete “prophylactically or”.**

**In claim 47, at line 4, delete “prophylactic or”.**

In claim 55, lines 1-2, delete “the presence of said genetic marker for susceptibility to myasthenia gravis is found” and insert therefore—said genetic marker for susceptibility to diabetes mellitus is present”.

In claim 59, lines 3-4, delete “cardiovascular disease, atherosclerosis or non-immune related cerebrovascular disease” and insert therefore—said non-immune-related disease--.

In claim 61, line 3, delete “cardiovascular disease, atherosclerosis or non-immune related cerebrovascular disease” and insert therefore—said non-immune-related disease--.

In claim 62, line 4, delete “cardiovascular disease, atherosclerosis or non-immune related cerebrovascular disease” and insert therefore—said non-immune-related disease--.

In claim 63, lines 1-2, delete “the presence of said genetic marker for susceptibility to myasthenia gravis is found” and insert therefore—said genetic marker for susceptibility to said non-immune-related disease is present”.

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In claim 63, line 5, delete “cardiovascular disease, atherosclerosis or non-immune related cerebrovascular disease” and insert therefore—said non-immune-related disease--.

In claim 65, lines 1-2, delete “cardiovascular disease, atherosclerosis or non-immune related cerebrovascular disease” and insert therefore—said non-immune-related disease--.

**In claim 70, at lines 2-3, delete “prophylactically or”.**

**In claim 70, at line 3, delete “prophylactic or”.**

In claim 71, lines 1-2, delete “the presence of said genetic marker for susceptibility to myasthenia gravis is found” and insert therefore—said genetic marker for susceptibility to Addison’s disease is present”.

**In claim 71, at line 4, delete “prophylactically or”.**

**In claim 71, at line 4, delete “prophylactic or”.**

**b) Amend the specification as follows:**

On page 11, at line 21, delete “QIAamp” and insert therefore—QIAAMP--.

On page 11, at line 30, delete “Eppendorf” and insert therefore—EPPENDORF--.

***Substance of the Interview concluding 23 September 2004***

6. On 03 September 2004 the examiner contacted Applicants' representative Gordon Kit to propose additional amendments to dependent claims 46-47 and 70-71. The examiner noted that the amendments were required pursuant to a "second pair of eyes" review of the application which concluded that the application did not meet the enablement requirement with regard to prophylaxis of myasthenia gravis or Addison's disease. Applicants' representative indicated that he would contact the applicants regarding the proposed amendments. The examiner noted that the application would have to be withdrawn from issue if authorization for the amendments could not be obtained shortly. On 15 September and 21 September 2004 the examiner placed follow up calls to applicants' representative; however, Applicants had not yet responded to the new proposals. On 23 September 2004 applicants' representative Drew Hissong contacted the examiner and authorized the proposed amendments. The examiner noted that the application was withdrawn from issue on 22 September 2004, and that she would re-allow the application, including a supplemental examiner's amendment, as soon as the application was returned from the Office of Publications.

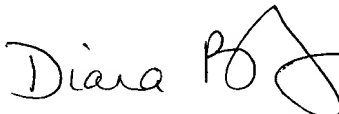
***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a long horizontal flourish extending to the right.

Diana B. Johannsen  
Primary Examiner  
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